IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant:	Saxon et al.	Docket No.:	39754-0672A
Serial No.:	09/847,208	Group Art Unit:	1644
Filing Date:	May 1, 2001	Examiner:	Phuong N. Nuynh

For: **FUSION MOLECULES AND TREATMENT OF IgE-MEDIATED ALLERGIC DISEASES**

SUPPLEMENTAL RESPONSE

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

The present Supplemental Response is filed concurrently with the filing of a Request for Continued Examination (RCE) of the above-identified patent application, requesting the entry of the previously unentered Amendment and Response filed on October 1, 2002, and Amendment and Request for Reconsideration filed on November 21, 2002.

In the Advisory Action dated April 9, 2003 the Examiner notes that the amendments to claim 87 and claim 77 raise the issue of new matter since the terms "portion" and "IgG inhibitor receptor" [sic] "have no clear supported [sic] in the specification and claims as originally filed." With regard to the phrase "portion" the Examiner further notes that it "could be as little as one amino acid, which now changes the scope of the claimed fusion molecule."

Applicants submit that the above reasons cited as a ground for non-entering the previous amendments are without foundation.

First of all, claim 87 does not simply refer to a "portion" of a constant region sequence, rather, it recites a constant region sequence, which "consists of the hinge-CH2-CH3 portion" of an IgG_1 heavy chain constant region. It is well know by those skilled in the art that the constant region of an IgG_1 heavy chain is composed of CH1, CH2, and CH3 domains, and a hinge region which is positioned between CH1 and CH2. In addition, the sequence of the hinge-CH2-CH3 portion of an IgG_1 heavy chain is known, and readily available, for example, from Kabat *et al.*, Sequences of Proteins of Immunological Interest, 5th Ed. Public Health Service, National Institute of Health, Bethesda, MD (1991), which is referred to on page 17, lines 22-23, and page

28, lines 26-27 of the specification as originally filed. As a specific reference for the human IgG_1 heavy chain constant region applicants additionally cite Ellison et al., *Nucl. Acids Res.* 10:4071-4079 (1982), and Takahashi et al., *Cell* 29:671-679 (1982) (see page 17, lines 25-26 of the specification as originally filed.) Accordingly, the phrase "the hinge-CH2-CH3 portion" is well defined, and could not be as little as one amino acid, as the Examiner suggests. Nor does the phrase go beyond the original scope of the specification, rather it is supported at a multitude of locations, including, by way of illustration, page 6, line 24, page 7, line 7, page 22, line 21.

Claim 77 recites an "IgG inhibitory receptor," which, contrary to the Examiner's assertion, has clear support in the specification as originally filed. IgG inhibitory receptors are discussed, for example, at page 3, lines 10-24; page 9, line 22; page 10, lines 10-12; and a specific clear definition is provided in the passage bridging pages 10 and 11. According to this definition:

> The term "IgG inhibitory receptor" is used to define a member of the inhibitory receptor superfamily (IRS), now know[n] or hereinafter discovered, that is capable of attenuating an FcεR-mediated response, regardless of whether it is mediated via IgE acting through a high-affinity IgE receptor, e.g. FcεRI, or a low affinity IgE receptor, or by another mechanism such as an autoantibody to the FcεR. The response preferably is an IgE-mediated allergic response, such as a typr I (immediate hypersensitivity) reaction but could include autoimmune reactions due to anti-FcεRIα-chain antibodies that have been reported in about half of the cases of chronic idiopathic urticaria."

In conclusion, the Examiner failed to cite any valid reason for refusing to enter and consider either of the amendments filed after final rejection. Indeed, Applicants submit that there is no valid reason for rejecting any of the claims pending, and respectfully request an early issuance of a Notice of Allowance.

Should the Examiner find that there are any further issues outstanding, a personal interview before issuance of a further Office Action is hereby requested. The Examiner is invited to call the undersigned attorney to arrange the time fore the personal interview.

Please charge any additional fees, including any fees for additional extension of time, or credit overpayment to Deposit Account No. 08-1641 (Attorney Docket No.: 39780-1618P2C4).

Please direct any calls in connection with this application to the undersigned at the number provided below.

Respectfully submitted,

Date: June 17, 2003

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